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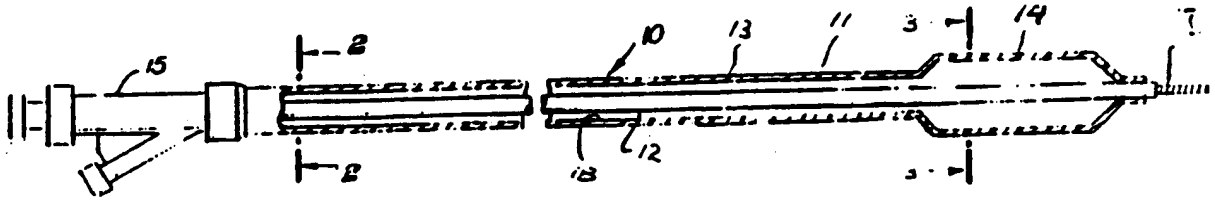

(57) Abstract

A balloon for dilatation catheters formed of fluoropolymer material which may be thermoplastic fluoropolymer and/or thermoplastic fluoroelastomer. The fluoropolymer material is melt processible, e.g. extruding and the like. One presently preferred fluoropolymer material is a copolymer of tetrafluoroethylene and ethylene.

INFLATABLE MEMBER FORMED OF FLUOROPOLYMERIC MATERIAL

BACKGROUND OF THE INVENTION

This invention relates to inflatable members for intravascular catheters such as dilatation catheters for percutaneous transluminal coronary angioplasty (PTCA).

PTCA is a widely used procedure for the treatment of coronary heart disease which includes advancing a balloon dilatation catheter into a patient's coronary artery and inflating the balloon on the distal end of the catheter within the stenotic region of the patient's artery to open up the arterial passageway and increase the blood flow through the artery.

To facilitate the advancement of the dilatation catheter into the patient's coronary artery, a guiding catheter having a preshaped distal tip is first percutaneously introduced into the cardiovascular system of a patient by the Seldinger technique through the brachial or femoral arteries. The catheter is advanced until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent the ostium. The guiding catheter is twisted or torqued from the proximal end, which extends out of the patient, to guide the distal tip of the guiding catheter into the ostium of the desired coronary artery. A balloon dilatation catheter may then be advanced through the guiding catheter into the patient's coronary artery until the balloon on the catheter is disposed within the stenotic region of the patient's artery. The balloon is inflated to open up the arterial passageway.

One type of catheter frequently used in PTCA procedures is an over-the-wire type balloon dilatation catheter, such as the SIMPSON ULTRA LOW PROFILE®, the HARTZLER ACX®, the HARTZLER ACX II®, the PINKERTON .018™ or the ACS TEN™ balloon dilatation catheter sold by the assignee of the present invention, Advanced Cardiovascular Systems, Inc. (ACS).

Another type of balloon dilatation catheter frequently used in PTCA procedures is the fixed-wire type dilatation catheter system which has a guidewire or guiding member secured within the catheter. The fixed-wire catheter provide a low profile, i.e. small transverse dimensions, because it does not have an inner tubular member which are characteristic of most commercially available over-the-wire dilatation catheters. Commercially available fixed-wire dilatation catheters include the HARTZLER EXCEL®, the HARTZLER LPS® and the SLALOM™ dilatation catheters sold by ACS.

Another type of dilatation catheter, the rapid exchange type catheter, was introduced by ACS under the trademark ACS RX® Coronary Dilatation Catheter. It is described and claimed in U.S. Patent 5,040,548 (Yock), U.S. Patent 5,061,273 (Yock) and U.S. Patent 4,748,982 (Horzewski *et al.*) which are incorporated herein by reference. This catheter has a short guidewire receiving sleeve or inner lumen extending through a distal portion of the catheter from a first guidewire port in the distal end of the catheter to a second guidewire port in the catheter spaced proximally from the inflatable member of the catheter. A slit may be provided in the wall of the catheter body which extends distally from the second guidewire port, preferably to a location proximal to the proximal end of the inflatable balloon. The structure of the catheter allows for the rapid exchange of the catheter without the need for an exchange wire or adding a guidewire extension to the proximal end of the guidewire. This catheter has been widely praised by the medical profession and it has met with much success in the market place because of the advantages of its unique design. The perfusion-type dilatation catheter was another type of dilatation catheter introduced into

the market place by ACS. This catheter, which can take the form of an over-the-wire, a fixed-wire or a rapid exchange catheter, has one or more perfusion ports proximal to the dilatation balloon in fluid communication with a guidewire receiving inner lumen and extending to the distal end of the catheter. A plurality of perfusion ports are preferably provided in the catheter distal to the balloon which are also in fluid communication with the inner lumen extending to the distal end of the catheter. When the balloon of this dilatation catheter is inflated to dilate a stenosis, oxygenated blood in the artery or the aorta or both, depending upon the location of the dilatation catheter within the coronary anatomy, is forced to pass through the proximal perfusion ports, through the inner lumen of the catheter and out the distal perfusion ports. The catheter provides oxygenated blood downstream from the inflated balloon to minimize ischemic conditions in tissue distal to the balloon. The perfusion of blood distal to the inflated balloon allows for long term dilatations, e.g. 30 minutes or even several hours or more. This type of catheter has likewise been highly praised by the medical profession and has met with much commercial success. Commercially available perfusion type dilatation catheters include the STACK PERFUSION® and the ACS RX PERFUSION™ dilatation catheters sold by ACS.

The balloons for prior dilatation catheters for PTCA procedures generally have been formed of relatively inelastic polymeric materials such as polyvinyl chloride, polyethylene, polyethylene terephthalate and polyolefinic ionomers. Nylon has been mentioned in the literature as an alternative inelastic material from which dilatation balloons can be made, but there has not been much commercial use of this material. The aforementioned prior art balloons are relatively inelastic so that upon inflation with liquid there is relatively little expansion of the balloon with increased internal pressures, even at very elevated levels. This ensures that the balloon will inflate to a predetermined size and will not overinflate, which might damage the artery.

In a deflated state, many of the prior inelastic dilatation balloons had wings which were heat formed to wrap about the longitudinal axis of the catheter in order to

present a lower profile, i.e. smaller transverse dimensions, and thereby facilitate the advancement of the catheter much deeper into the patient's coronary anatomy and the crossing of much tighter stenoses. In some instances, such as with balloons formed of polyethylene terephthalate, the wings may not readily be heat formed, which exacerbate the problems of advancing the balloon through the patient's arterial system. However, when the prior balloons were inflated to dilatate the stenosis, the wings of the deflated balloon would unfold applying very high shear stresses to the stenosed artery. The high levels of shear stress may cause dissections in the arterial lining which could interfere with the dilatation procedure. Prior efforts in applying a lubricous coating onto the surface of the balloon with silicone material have shown that the coating can moderate the shear stress applied to the artery wall. However, forming an effective lubricous coating on commercially available balloon materials has been found to require complicated processing. Homopolymers of tetrafluoroethylene (Teflon® from DuPont Polymers), while having excellent lubricity, strength and biocompatibility, are generally not melt processable into suitable balloons.

What has been needed and heretofore unavailable is a thin walled, high strength inflatable member for intravascular catheters having an effective lubricous surface which does not require difficult manufacturing procedures. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

This invention is directed to an improved balloon formed of a fluoropolymer material and having high strength and a durable lubricous surface which is particularly suitable for an intraluminal catheters.

The invention is generally directed to an inflatable member or balloon formed of fluoropolymer material and more specifically to a melt processable fluoropolymer. The balloon may be used on an intraluminal catheter having an elongated catheter shaft with at least one inner lumen adapted to direct inflation liquid

therethrough to the interior of the inflatable member or balloon on the distal extremity of the catheter shaft. The inflatable member or balloon is suitable to dilate body lumens such as stenotic coronary and peripheral arteries, prostatic urethras and the like.

The balloon of the invention generally is formed of melt processable, fluoropolymer material which may be a thermoplastic fluoropolymer, a thermoplastic fluoroelastomer or a blend of one or more thermoplastic fluoropolymers and one or more thermoplastic fluoroelastomer. A blend of such components may range from about 10 to about 90% thermoplastic fluoropolymer and from about 90 to about 10% thermoplastic fluoroelastomer, preferably about 40 to about 80% thermoplastic fluoropolymer and about 20 to about 60% thermoplastic fluoroelastomer. Other preferred blends include about 10 to about 90% thermoplastic fluoropolymer and thermoplastic fluoroelastomer and about 90 to about 10% fluoroelastomer, more preferably about 40 to about 80% thermoplastic fluoropolymer and thermoplastic fluoroelastomer and about 60 to about 20% fluoroelastomer. As used herein all percentages are weight percent unless noted otherwise.

The thermoplastic fluoropolymer comprising at least 4 mole%, preferably at least 20 mole%, of monomer units selected from the group consisting of -(-CF_2-CF_2-)- and -(-CF_2-CHR-)-, where -R is selected from the group consisting of -H, -F, -CF_3, -CH_3 and -OCF_3. The thermoplastic fluoropolymer material may be homopolymers or copolymers of such monomer units or blends of homopolymer or copolymer segments formed of the aforesaid monomer units. Non-fluoride monomer units may be included in the thermoplastic fluoropolymer material in amounts up to 60 mole%. One presently preferred thermoplastic fluoropolymer material is a copolymer of tetrafluoroethylene (TFE) with sufficient amounts of other monomer units to reduce its crystallinity and render it melt processible. Such other monomer units include perfluoropropylvinyl ether (PPVE), -(-CF_2-$CF(O(CF_2)_2)$-CF_3-)-, perfluoromethylvinyl ether (PMVE), -(-CF_2=$CF(OCF_3)$-)-, hexafluoropropylene

(HPF), -(-CF_2=$CF(CF_3$-)-, and ethylene, -(-CH_2-CH_2-)-. The copolymers with vinyl ethers mentioned above are available from DuPont Polymers under the trademark Teflon® PFA, from Ausimont U.S.A. Inc. under the trademark Hyflon® and from Daikin under the trademark Neoflon®. The copolymer with HFP is available from DuPont Polymers under the trademark Teflon® FEP and the copolymer with ethylene is available from DuPont Polymers under the trademark TEFZEL®, from Aschi Glass co. under the trademark Aflon® COP, from Daikin under the mark Neoflon® EP and from Ausimont under the mark Halon ET®.

Another suitable class of thermoplastic fluoropolymers include homopolymers of vinylidene fluoride and copolymers of vinylidene fluoride and one other monomer unit such as HFP or PMVE as mentioned above. These polymers are available as Kynar® from Elf Atochem, Hyar® from Ausinmmont, Neoflon® from Daikin, KF® from Kureha Chemical Industry Co. Ltd. and Solef® from Solvay & Cie, S.A. The preferred thermoplastic fluoropolymer contains about 25 to about 60 mole% ethylene and about 7.5 to about 40 mole% of tetrafluoroethylene. Up to about 30 mole%, preferably about 0.5 to about 10 mole% of a monomer may be included, such as perfluoroalkylvinyl or vinlyidene compounds, perfluoroalkyl ethylenes and perfluoroalkoxy vinyl compounds

Suitable thermoplastic fluoroelastomers which are presently preferred, include Dai-el® T530, T550 and T630 available from Daikin, described in U.S. Patent 4,935,467 (Cheng *et al.*), which are a thermoplastic fluoroelastomers having hard segments containing ethylene, tetrafluoroethylene and a third monomer such as hexafluoropropylene 3,3,3-tri-fluoropropylene1; 2-trifluoromethyl-3,3,3-trifluoro-propylene-1; or perfluoro (alka/vinyl ether) and soft segments containing vinylidene fluoride and hexafluoropropylene units, and may include tetrofluoroethylene. The content of the latter Cheng *et al.* patent is incorporated herein in its entirety by reference. Other thermoplastic fluoroelastomers

include CEFRAL SOFT (e.g. G120, G150 and G180) from Central Glass Co., Ltd. which are believed to be copolymers of vinylidene fluoride with HPF and or TFE.

The fluoroelastomers which may be used to form the balloon of the invention include those having at least one elastomeric segment comprising vinylidene fluoride, hexa- or pentafluoropropylene and/or tetrafluoroethylene repeating units (e.g. Viton® from DuPont, Fluorel® from 3M and Dai-el® from Daikin, or perfluoro(alkyl vinyl ether) such as PPVE and PMVE previously referred to, tetrafluoroethylene and vinylidene fluoride repeating units (e.g. Viton® from DuPont), or tetrafluoroethylene and propylene (e.g. Aflas® from Asahi Glass) or tetrafluoroethylene and PMVE previously referred to (Kalrez® from DuPont).

The polymers based upon tetrafluoroethylene and ethylene monomers as repeating units may be highly crystalline and exhibit stress-cracking at elevated temperatures. As a result it is preferred to modify the properties by adding a third monomer such as perfluoroalkylvinyl or vinlyidene compounds, perfluoroalkyl ethylenes and perfluoroalkoxy vinyl compounds. Particularly preferred third monomers are perfluoroisobutylene; hexafluoropropylene; perfluorobutyl ethylene; 3,3,3,-tri-fluoropropylene-1; 2-tri-fluoromethyl-3,3,3 trifluoro-propylene-1; and perfluoro (alkylvinylether).

The balloon of the invention may be readily made by forming a tubular product of the desired fluoropolymeric material using conventional melt processing techniques, such as extrusion or co-extrusion. After the tubular product of the desired composition is formed, it may be cross-linked and then blown in a conventional fashion into a balloon.

The fluoropolymers may be cross-linked by the use of a suitable cross-linking agent such as a peroxide or an amine, or by irradiation with gamma or electron beam radiation or both. It is preferable to incorporate a cross linking agent in amounts ranging from about 0.1 to about 2 %, preferably about 0.1 to about 1% into the mixture containing the fluoromonomer before it is formed to facilitate cross-

linking upon irradiation. Suitable cross-linking agents include components having carbon-carbon unsaturation, e.g. ethylenic double bonds, such as allyl, methallyl, propargyl or vinyl groups. Preferred agents include triallyl cyanurate, triallyl isocyanurate, triallyl trimellitate, triallyl trimesate, tetraallyl pyromellitate and the diallyl ester of 1,1,3-trimethyl-5-carboxy-3-(p-carboxyphenyl) indane. See also the disclosure found in U.S. Patent 3,763,222, U.S. Patent 3,840,619, U.S. 3,894,119 and other references described in U.S. Patent 4,935,467 which has been incorporated herein by reference. Various additives, such as antioxidants and stabilizer such as disclosed in U.S. Patent 4,935,467, may also be incorporated into the fluoropolymer material before it is formed.

Additional information pertaining to suitable fluoropolymers and fluoroelastomers may be found in Tetrafluoroethylene Polymers, Subash V. Gangal, Encyclopedia of Polymer Science, Volume 16, Second Edition, Copyright 1989 by John Wiley and Sons, Inc. pp. 577-62; Fluoropolymers, Organic, D. Peter Carlson and Walter Schmeigel, Ullmann's Encyclopedia of Industrial Chemistry, 5th Edition, Copyright 1988 by VCH Verlagsgessellschaft mbH, pp. 393-429 and Vinylidene Fluoride Polymers, Julius E. Dohany and James S. Humphrey, Encyclopedia of Polymer Science and Engineering, Volume 17, Second Edition, Copyright 1989 by John Wiley and Sons, Inc., pp. 532-548, which are incorporated herein in their entirety.

The balloons of the invention exhibit good flexibility and very high tensile strength at body temperature (37°C) and are characterized by very low coefficients of friction. As a result, when performing dilatations with catheters having balloons of the present invention, the morbidity rates, e.g arterial dissections and other arterial problems, are quite low. Typical tensile strengths range from about 7 to about 15 ksi, preferably about 8 to about 13 ksi. The expansions of the balloon range from about .25 mm to about .75 mm at bursting pressures (can we express this in more relative terms or units, e.g. %. These and other advantages of the invention will become more

apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view, partially in section, of an over-the-wire dilatation catheter embodying features of the invention.

Fig. 2 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines of 3-3.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates a dilatation catheter 10 of the invention which includes an elongated catheter shaft 11 comprising an inner tubular member 12 and an outer tubular member 13, a balloon or inflatable member 14 formed of fluoropolymer materials and an adapter 15. The inner tubular member 12 has an inner lumen 16 which is adapted to receive the guidewire 17 and defines with the outer tubular member 13 an annular lumen 18 which is adapted to direct inflation fluid to the interior of the balloon 14. The arm 19 of the adapter 15 directs inflation fluid from a source not shown into the annular lumen.

In the embodiment shown in the drawings, the shaft 11 and the balloon 14 are formed of the same fluoropolymer material. In other embodiments the balloon 14 may be formed of the desired fluoropolymeric material and be secured by its proximal end to the distal end of the shaft 11 which may be formed of other material such as polyethylene.

Suitable thermoplastic fluoropolymers include polyvinylidene fluoride such a Foraflon® 1000HD and 2500HD which is available from Atochem Corp and Kynar® 760 which is available from the Pennwalt Corporation and copolymers of ethylene and

tetrafluoroethylene such a Tefzel® which is available from E.I. DuPont, deNemours & Co.

The materials of construction of other catheter components such as the inner tubular member 12 and the adapter 15 may be formed of conventional materials, e.g. polyethylene, polyvinyl chloride, polyimide and the like. The means used to join the various catheter components may be conventional such as by heat bonding, heat shrinking or use of a suitable adhesive. The various catheter components will generally be of conventional size depending upon the intended end use.

EXAMPLE 1

The following example is given to illustrate the manufacture of a balloon of the invention formed of fluoropolymeric materials. Polyvinylidene fluoride (Kynar 760) was extruded into tubing having an OD of about 0.03 inch (0.76 mm) and an ID of about 0.018 inch (0.46 mm) and cooled in a trough of cold water (35° F). The tubing was irradiated at 10 Mrads by gamma radiation and then was placed within a capture tube having an inner diameter of about 3 mm, the desired inflated diameter for the balloon. The irradiated tubing and the surrounding capture tube was heated in a heater to the desired temperature for blowing, removed from the heater, tugged slightly and then blown into a balloon with air at about 1-2 psi at a temperature of about 424° F. It was found that the extruded tubing should be necked slightly before blowing to avoid significant differences in wall thickness in the final product. Five balloons were formed in this manner with lengths ranging from about 0.375 to about 0.625 inch (9.5 - 10.6 mm). The inflated balloon diameters ranged from about 0.100 to about 0.112 inch (2.5 - 2.8 mm) and the double wall thicknesses ranged from about 0.0005 to about 0.003 inch (0.013 - 0.076 mm). The balloons were found to be very suitable for use in dilatation catheters adapted to perform PTCA. The tensile strengths of these balloons in the hoop direction ranged from about 8 to about 10 ksi.

EXAMPLE 2

A fluoropolymer commercially available as Tefzel 280 from DuPont Polymers was melt processed to a tubular member of the same transverse dimensions as in the first example, irradiated at 40 Mrads and then blown into a 2.4 mm balloon (0.0016 inch double wall thickness) at a temperature of 460° F. and a internal pressure of 31 psi. Upon testing the balloon ruptured at a pressure of 150 psi. The balloon was found to be suitable for use on a dilatation catheter for angioplasty procedures as described herein.

EXAMPLE 3

A fluoropolymer commercially available as FORAFLON 1000D available from Atochem Corp. was melt processed to a tubular member of the same transverse dimensions as in the first example, irradiated at 40 Mrads and then blown into a 3.0 mm balloon (0.0013 inch double wall thickness) at a temperature of 450° F. and a internal pressure of 15 psi. Upon testing the balloon ruptured at a pressure of 140 psi. The balloon had a tensile strength of 12.7 ksi and was found to be suitable for use on a dilatation catheter for angioplasty procedures as described herein.

While the detailed description of the invention has been described herein in terms of presently preferred embodiments comprising an over-the-wire balloon dilatation catheter for PTCA, those skilled in the art will recognize that the balloon of the invention may be employed in essentially any balloon catheter adapted for dilatation. Moreover, the balloon may be utilized on catheters adapted to dilate prostatic urethras and other body lumens. Likewise, other modifications and improvements may be made to the present invention without departing from the scope of the invention.

WHAT IS CLAIMED IS:

1. A balloon dilatation catheter having

a) an elongated catheter shaft with at least one inner lumen extending therein; and

b) an inflatable member which is formed of fluoropolymer material and which has an interior in fluid communication with the inner lumen extending within the catheter shaft.

2. The balloon dilatation catheter of claim 1 wherein the fluoropolymer material is melt processible.

3. The balloon dilatation catheter of claim 2 wherein the fluoropolymer material is selected from the group consisting of homopolymers and copolymers of thermoplastic fluoropolymers and thermoplastic fluoroelastomers.

4. The balloon dilatation catheter of claim 3 wherein the fluoropolymer material includes a fluoroelastomer and thermoplastic fluoroelastomer.

5. The balloon dilatation catheter of claim 3 wherein at least 4 mole% of the thermoplastic fluoropolymer material is tetrafluoroethylene monomer units.

6. The balloon dilatation catheter of claim 3 wherein at least 20 mole% of the thermoplastic fluoropolymer material is tetrafluoroethylene monomer units.

7. The balloon dilatation catheter of claim 3 where the thermoplastic fluoropolymer material is a copolymer of tetrafluoroethylene monomer units and

monomer units selected from the group consisting of perfluoropropylvinyl ether (-(-CF_2-$CF(O(CF_2)_2)$-CF_3-)-), perfluoromethylvinyl ether (-(-CF_2-$CF(CF_3)$-)-), hexafluoropropylene (-)-CF_2-CF_2-CF_2-)-), and ethylene, (-(-CH_2-CH_2-)-).

8. The balloon dilatation catheter of claim 3 wherein the fluoropolymer material contains tetrafluoroethylene and ethylene monomer units.

9. The balloon dilatation catheter of claim 3 wherein the thermoplastic fluoropolymer material has a mole ratio of about 35-60 ethylene monomer units to about 65-40 tetrafluoroethylene monomer units.

10. The balloon dilatation catheter of claim 3 wherein the thermoplastic fluoropolymer is selected from the group consisting of homopolymers and copolymers of tetrafluoroethylene and the fluoroelastomer is selected from the group consisting of homopolymers and copolymers of the monomer -(-CF_2-CHR-)-, where R is selected from the group consisting of -H, -F, -CF_3, -CH_3 and -OCF_3, and blends of such homopolymers and copolymers.

11. The balloon dilatation catheter of claim 3 wherein the thermoplastic elastomeric fluoropolymer is formed of a block copolymer of tetrafluoroethylene and -(-CF_2-CHR-)-, where R is selected from the group consisting of -H, -F, -CF_3, -CH_3 and -OCF_3, and blends of such homopolymers and copolymers.

12. The balloon dilatation catheter of claim 3 wherein the amount of thermoplastic fluoropolymer ranges from about 10 to about 90% of the fluoropolymer material and the amount of thermoplastic elastomeric fluoropolymer ranges from about 90 to about 10% of the fluoropolymer material.

13. The balloon dilatation catheter of claim 1 wherein the catheter shaft and the inflatable member are formed of the same fluoropolymer material.

14. The balloon dilatation catheter of claim 1 wherein the fluoropolymer material is a homopolymer or a copolymer of vinylidene fluoride.

15. The balloon dilatation catheter of claim 14 wherein monomer units forming a copolymer of vinylidene fluoride are selected from the group consisting of hexafluoropropylene and perfluoromethylvinyl ether.

16. An inflatable balloon which is formed of fluoropolymer material.

17. The inflatable balloon of claim 16 wherein the fluoropolymer material is melt processible.

18. The inflatable balloon of claim 17 wherein the fluoropolymer material is selected from the group consisting of homopolymers and copolymers of thermoplastic fluoropolymers and thermoplastic fluoroelastomers .

19. The balloon dilatation catheter of claim 18 wherein the fluoropolymer material includes a fluoroelastomer in addition to the thermoplastic fluoroelastomer.

20. The inflatable balloon of claim 18 wherein at least 4 mole% of the thermoplastic fluoropolymer material is tetrafluoroethylene monomer units.

21. The balloon dilatation catheter of claim 18 wherein at least 20 mole% of the thermoplastic fluoropolymer material is tetrafluoroethylene monomer units.

22. The balloon dilatation catheter of claim 18 where the thermoplastic fluoropolymer material is a copolymer of tetrafluoroethylene monomer units and monomer units selected from the group consisting of perfluoropropylvinyl ether (-(-CF_2-$CF(O(CF_2)_2)$-CF_3-)-), perfluoromethylvinyl ether (-(-CF_2-$CF(CF_3)$-)-), hexafluoropropylene (-)-CF_2-CF_2-CF_2-)-), and ethylene, (-(-CH_2-CH_2-)-).

23. The inflatable balloon of claim 18 wherein the fluoropolymer material contains tetrafluoroethylene and ethylene monomer units.

24. The balloon dilatation catheter of claim 18 wherein the thermoplastic fluoropolymer material has a mole ratio of about 35-60 ethylene monomer units to about 65-40 tetrafluoroethylene monomer units.

25. The inflatable balloon of claim 18 wherein the thermoplastic fluoropolymer is selected from the group consisting of homopolymers and copolymers of tetrafluoroethylene and the fluoroelastomer is selected from the group consisting of homopolymers and copolymers of the monomer -(-CF_2-CHR-)-, where R is selected from the group consisting of -H, -F, -CF_3, -CH_3 and -OCF_3, and blends of such homopolymers and copolymers.

26. The inflatable balloon of claim 18 wherein the thermoplastic elastomeric fluoropolymer is formed of a block copolymer of tetrafluoroethylene and -(-CF_2-CHR-)-, where R is selected from the group consisting of -H, -F, -CF_3, -CH_3 and -OCF_3, and blends of such homopolymers and copolymers.

27. The inflatable balloon of claim 18 wherein the amount of thermoplastic fluoropolymer ranges from about 10 to about 90% of the fluoropolymer material and

the amount of thermoplastic elastomeric fluoropolymer ranges from about 90 to about 10% of the fluoropolymer material.

28. The inflatable balloon claim 16 wherein the fluoropolymer material is a homopolymer or a copolymer of vinylidene fluoride.

29. The inflatable balloon of claim 28 wherein monomer units forming a copolymer of vinylidene fluoride are selected from the group consisting of hexafluoropropylene and perfluoromethylvinyl ether.

30. The inflatable balloon of claim 17 wherein the fluoroelastomer has hard segments and soft segments.

31. The inflatable balloon of claim 30 wherein the hard segments contain ethylene, tetrafluoroethylene and hexafluoropropylene monomer units.

32. The inflatable balloon of claim 30 wherein the soft segments contain vinylidene fluoride, tetrafluoroethylene and hexafluoropropylene monomer units.

33. The balloon of claim 11 wherein the thermoplastic fluoropolymer material includes a monomer of methyl methacrylate.

34. The balloon dilatation catheter of claim 12 wherein the thermoplastic fluoropolymer is a copolymer of tetrafluoroethylene and ethylene.

35. The balloon dilatation catheter of claim 9 wherein the thermoplastic fluoropolymer material includes up to about 30 mole% of a third monomer selected from the group consisting of perfluoroisobutylene; hexafluoropropylene; perfluorobutyl

ethylene; 3,3,3,-tri-fluoropropylene-1; 2-tri-fluoromethyl-3,3,3 trifluoro-propylene-1; and perfluoro(alkylvinylether).

36. The balloon dilatation catheter of claim 35 wherein the thermoplastic fluoropolymer material includes from about 0.5 to about 10 mole% of the third monomer.

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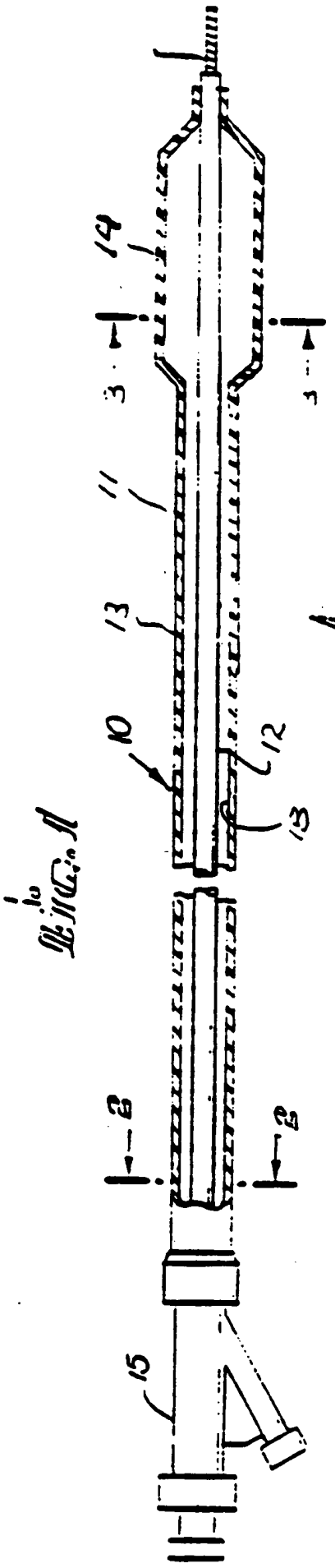

FIG. 1

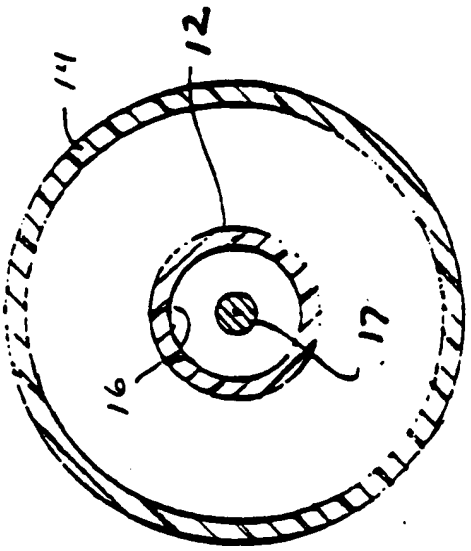

FIG. 3

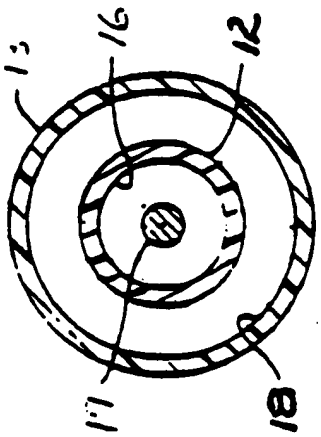

FIG. 2

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 93/06756

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61L29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE,A,35 17 732 (JACOBSON O.) 20 November 1986 see page 5, line 1 - line 24; claims 1-5	1-36
A	US,A,4 335 723 (PATEL B.C.) 22 June 1982	
P,Y	WO,A,92 19306 (GAHARA W.J.) 12 November 1992 see claim 7	1-36
P,Y	WO,A,92 19311 (BAXTER INTERNATIONAL) 12 November 1992 see claims 11,12	1-36

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
22 October 1993	04. 11. 93
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	**Authorized officer** PELTRE, C

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A-3517732	20-11-86	NONE	
US-A-4335723	22-06-82	AU-A- 3099077	31-05-79
		BE-A- 861234	16-03-78
		DE-A- 2752702	01-06-78
		FR-A- 2371933	23-06-78
		JP-A- 53069488	20-06-78
		NL-A- 7712751	30-05-78
		SE-A- 7713365	27-05-78
		US-A- 4119099	10-10-78
WO-A-9219306	12-11-92	US-A- 5195970	23-03-93
WO-A-9219311	12-11-92	NONE	